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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,644

03/17/2005

Takeshi Ito

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20529 7590 08/17/2009
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EXAMINER

MERCIER, MELISSA S

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

08/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,644	Applicant(s) ITO ET AL.	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8-19-08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Change of Examiner

The examiner assigned to the instant application has changed. The new examiner is Melissa Mercier. Contact information is provided at the end of this Office Action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 20, 2009 has been entered.

Claims 1-3 and 8-10 remain pending in this application.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on August 19, 2008 is acknowledged. A signed copy is attached to this office action.

Withdrawn Rejections/Objections

Claim Rejections - 35 USC § 103

The rejection of claims 1-6 and 8-10 under 35 U.S.C. 103(a) as being unpatentable over Terahara et al. (WO 02/38139) as evidenced by US 2004/0028724,

which is the English equivalent has been withdrawn in view of Applicants amendment to claim 1 incorporating the contents of claim 7.

Maintained Rejections/Objections

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (EP 1 201 232).

Chono discloses a patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with an adhesive agent (organic acid) and oxybutynin and/or a pharmaceutically acceptable salt thereof [0014], [0015] wherein the adhesive layer comprises an acrylic polymer substantially free of both carboxyl group and hydroxyl group in the molecule, and a rubber polymer [0030]. Chono also discloses the acrylic polymer being 10-98% by weight and the rubber polymer being 15-50% by weight [0031].

Chono discloses the acrylic polymer is copolymer of 2-ethylhexyl acrylate and vinyl acetate monomers, and the rubber polymer is styrene-isoprene-styrene block copolymer [0030], [0031].

Chono discloses the adhesive layer is compounded with oxybutynin hydrochloride [0015]. Chono additionally discloses the adhesive agent comprises an organic acid (acetic acid) [0017].

Chono. fails to expressly disclose the weight content ratio of the acrylic polymer to the rubber polymer being only from 1:4 to 1:19. However, with the ranges described above, the weight ratio content of the acrylic polymer to the rubber polymer can be 1:4.

It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to optimize the formation of the adhesive layer and sufficient skin permeability of the drug. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues:

*the claims matrix has superior properties over those of the Chono reference.

Applicant is again reminded that the data of Tables 1 and 2 are not commensurate in scope to the claimed invention. The claims recite 2 different acrylic polymers; however, applicant has provided data to only one of them. No evidence has been submitted to show that the terpolymer would have the same properties as the copolymer in the recited claims.

Furthermore, it is noted that Chono discloses the ratio of about 1:4 which overlaps the instant claims. Applicant has further presented arguments regarding the excipients being in identical amounts, however, table 2 shows otherwise. The excipients are in varying amounts.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, and 8-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6, 8, 9-11, and 13-14 of copending Application No. 10/469,612. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a patch comprising a backing layer or a support (which are identical), a drug, an adhesive layer comprising identical acrylic polymers and styrene copolymers, and a tackifier. The subject matter covered in either patent would cover the subject matter of the other.

The only difference between the two sets of claims is the recitation of a specific weight ratio of acrylic polymer to styrene polymer, however, It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic

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polymer to the rubber polymer to optimize the formation of the adhesive layer and sufficient skin permeability of the drug. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant has argued that the claims in the '612 application do not recite the weight ratio of the acrylic polymer to the styrene polymer and is thus patentably distinct from the instant claims. The Examiner respectfully disagrees. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to optimize the formation of the adhesive layer and sufficient skin permeability of the drug. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Applicant has not presented any arguments or evidence to indicate that the ratio is not easily optimizable through routine experimentation.

Newly Applied Rejections

Claim Rejections - 35 USC § 103

Claims 1-3 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle et al. (US Patent 6,210,705) in view of Sablotsky (US Patent 4,994,267) and further in view of Gale (US Patent 5,614,211).

Mantelle discloses a topical composition of a drug comprising:

an adhesive layer laid on a support containing an adhesive base and a drug (Example 1) and an acrylate-vinylacetate copolymer (Example 16). Mantelle discloses the disclosed formulation is beneficial because it can deliver active agents transdermally and achieve substantially zero order kinetics over a period of at least 10 hours (column 2, lines 53-56).

Mantelle does not disclose the particular styrene polymer or an explicit disclosure of a formulation comprising an acrylic polymer and a rubber based polymer. Mantelle does however disclose styrene block copolymers (column 4, line 58), and teaches a blend of an acrylic polymer and a rubber based polymer as a possible combination (column 4, lines 46-67).

Sablotsky discloses a dermal composition comprising a drug, an acrylate polymer, a rubber polymer and a tackifying agent (column 4, lines 12-14). Sablotsky teaches styrene-isoprene-styrene block copolymers may be used in the composition (column 5, lines 34-36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the styrene copolymer of Sablotsky in the

composition of Mantelle in order to provide a transdermal application which can achieve substantially zero order kinetics over a period of at least 10 hours.

The combination of Mantelle and Sablotsky does not disclose the use of oxybutynin as a drug.

Gale discloses the use of oxybutynin for transdermal delivery.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated oxybutynin as an active agent in transdermal delivery device as disclosed by Mantelle and Sablotsky since it is known to be routinely administered transdermally as evidenced by Gale.

The cited references fail to expressly disclose the weight content ratio of the acrylic polymer to the rubber polymer being only from 1:4 to 1:19. However, with the ranges described above, the weight ratio content of the acrylic polymer to the rubber polymer can be 1:4. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to optimize the formation of the adhesive layer and sufficient skin permeability of the drug. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is

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(571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615